

REMARKS

Claims 1-7, 11, 12, 15-21, 35-37, 39, 41, 43, and 45 were pending in the present Application before entrance of this Amendment. Claims 36, 37, 39, 41, 43, and 45 have been withdrawn from consideration by the Examiner at this time. Claims 1-7, 11, 12, 15-21, and 35 stand rejected by the Examiner. Claim 1 is amended by the present Amendment. No claims have been canceled, and no new claims have been added. Support for the amendment to claim 1 can be found on page 2, line 23. Applicant submits that no new matter has been added to this Application by the present Amendment.

Each of the rejections levied by the Examiner in the outstanding Office Action is addressed in turn below.

Rejections under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1-7, 15-21, 35, and 49 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,245,776 ("the '776 patent"). The '776 patent discloses a pharmaceutical formulation of an immune response modifier (IRM) for administration to the cervix of a subject for the treatment of such conditions as cervical dysplasia.

Amended independent claim 1 and independent claim 35 both claim an aqueous sprayable formulation for nasal delivery having a viscosity of less than 100 cps at room temperature. Respectfully, the Examiner has not pointed to any teaching or suggestion in the '776 patent of an aqueous sprayable formulation for nasal delivery having a viscosity of less than 100 cps at room temperature. The '776 patent instead discloses pharmaceutical formulations having viscosities on the order of 10^5 cps. See Tables 1-3 of the '776 patent. (Table 4 indicates that viscosity is given in $\times 10^5$ cps; however, this seems to be an error given the viscosities reported for the same formulations in Table 3. Table 4 should read " $\times 10^5$ cps" rather than " $\times 10^{-5}$ cps".) Nowhere does the '776 patent teach or suggest a formulation having a viscosity of less than 100 cps at room temperature. Additionally, the claimed subject matter is further distinguished from subject matter of the '776 patent in that the claimed formulations are sprayable. The formulations of the '776 patent, having viscosities on the order of 10^5 cps (similar to honey), would not be sprayable.

Accordingly, since the '776 patent does not teach an aqueous sprayable formulation having a viscosity of less than 100 cps at room temperature, Applicant respectfully submits that the '776 patent does not anticipate the presently claimed invention and requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 103(a)

The Examiner has also rejected claims 1-7, 15-21, 35, and 49 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,331,539 ("the '539 patent") and U.S. Patent No. 6,083,505 ("the '505 patent") in view of the '776 patent. Applicant respectfully submits that none of the cited references teach or suggest an aqueous sprayable formulation for nasal delivery having a viscosity of less than 100 cps at room temperature, as recited in independent claims 1 and 35. As discussed above, the '776 patent discloses pharmaceutical formulations having viscosities on the order of 10^5 cps and does not teach or suggest a formulation having a viscosity of less than 100 cps at room temperature. Since the '776 patent is directed to high-viscosity formulations for treatment of cervical conditions, one of ordinary skill in the art would have had no reason to modify the '776 patent to produce a formulation having a viscosity of less than 100 cps at room temperature for nasal delivery. Additionally, neither the '539 patent nor the '505 patent disclose any formulation having a viscosity of less than 100 cps at room temperature. In fact, the '539 and '505 patents do not disclose any particular formulations much less disclose the viscosity of any formulation being less than 100 cps at room temperature. Thus, combining the '539, '505, and '776 patents would not have resulted in the claimed invention. Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness and requests that this rejection be withdrawn.

In view of the above Amendment and Remarks, Applicant believes the pending Application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge it, or credit any overpayment, to our Deposit Account No. 23/2825, under Docket No. C1271.70077US00, from which the undersigned is authorized to draw.

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Respectfully submitted,

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